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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/799,910	02/13/97	FALB D	7853-067

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EXAMINER	
NGUYEN, D	
ART UNIT	**PAPER NUMBER**
1633	29

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

5)

1- File Copy

000; 485-188/25268

Office Action Summary	Application No. 08/799,910	Applicant(s) FALB, DEAN A.	
	Examiner Dave Nguyen	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2000* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *103-117* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *104* is/are allowed.

6)☒ Claim(s) *103,and 105-117* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

Claims 103, 105-107, and claims 108-117 have been added by the amendment filed August 24, 2000.

Claims 103-117, to which the following grounds of rejection remain and/or are applicable, are pending.

The specification is objected to under 37CFR 1.52(b), which requires that the pages of the specification be numbered starting with "1". Pages i-iv of the specification do not conform with the arrangement of the specification according to MPEP 608.01(a), particularly since the item (b) "Cross Reference to Related Applications" does not appear on the first paragraph of the specification, and since the title headings appear both at page i and page 1 of the specification. It is suggested that pages i-iv should be deleted or removed from the specification. Should applicant intends to keep pages I-vi as part of the specification, Applicant must amend the specification to delete any reference to page numbers since a patent if issued from the as-filed application is not arranged by page numbering but by column numbering.

Claim Rejections - 35 USC § 112

> The following is a quotation of the first paragraph of 35 U.S.C. § 112:
> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 103, and 105-117 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention encompassing any and/or all polynucleotide sequences including coding regions, introns, 5' and 5' regulatory elements, other untranslated regions, full length ORFs, structurally unrelated DNA sequences, partial DNA sequences of genes other than nucleotides 211-468 of SEQ ID NO: 9, and any and/or all DNA encoded polypeptides which are upregulated in monocytes under conditions of oxidized LDL treatment.

The claims encompass a genus of "polynucleotide sequences" comprising nucleotides corresponding to coding regions, introns, 5' and 3' regulatory elements, and untranslated regions of the genes, full-length encoded cDNA and/or genes (claim 103), and structurally unrelated DNAs, and partial DNA sequences of genes other than nucleotides 211-468 of SEQ ID NO: 9 (claim 105).

An adequate written description of the invention defined by the claims, *e.g.* genus of polynucleotide sequences and/or genes and/or unrelated DNA sequences that hybridize to nucleotides 211-468 of SEQ ID NO: 9, requires more than a mere statement that it is part of the invention and reference to a knowledge in the art as to a partial open reading frame (ORF) as set forth in SEQ ID NO: 9; what is required is the knowledge in the prior art and/or a description as to the availability of a representative number of species of the claimed genus. The specification describes an isolated cDNA fragment (nucleotides 211-468 of SEQ ID NO: 9) obtained from a human endothelial cell library which was induced under shear stress conditions. Nucleotides 211-468 of SEQ ID NO: 9 is asserted to be homologous to the mouse gly96 cDNA, which encodes a cytokine inducible glycosylated protein expressed in mouse lung, tested, and uterus. Further, the specification indicates that it would be reasonable to infer that the partial sequence of nucleotides 211-468 of SEQ ID NO: 9 can be used as a probe to isolate the mouse gly96 cDNA. A search of prior art indicates that nucleotides 211-468 of SEQ ID NO: 9 as of Feb. 16, 1996 is novel and unobvious and no associated genomic clones have been identified, and that other than the mouse gly96 cDNA, no other unrelated cDNA sequences has greater than 50% similarity to the disclosed nucleotides. A review of the specification indicates that elements which are not particularly described include coding regions, introns, 3' and 5' regulatory elements, other untranslated regions, full length ORFs, structurally unrelated DNAs, and partial DNA sequences of genes other than nucleotides 211-468 of SEQ ID NO: 9. There is no actual reduction to practice the full scope of the claimed invention, clear depiction of the claimed invention in the drawings or complete detailed description of the structure. Considering all disclosed distinguishing identifying characteristics, there is a disclosure of only nucleotides 211-468 of SEQ ID NO: 9 as well as the function of the nucleotides as a probe for the mouse gly96 cDNA.

However, there is no known or disclosed correlation between this function and the structure of the non-described coding regions, introns, 3' and 5' regulatory elements, other untranslated regions, full length ORFs, structurally unrelated DNAs, and partial DNA sequences of genes other than nucleotides 211-468 of SEQ ID NO: 9. Furthermore, there is no additional disclosure of physical and/or chemical properties.

In addition and with respect to newly amended and added claims directed to any DNA encoding amino acids 71-157 of SEQ ID NO: 10 (referred as the fchd605 polypeptide) wherein the polypeptide is upregulated in monocytes under conditions of oxidized LDL treatment, and to any DNA that hybridizes under specified highly stringent hybrization conditions to the polynucleotide of claim 104, wherein the DNA encodes any polypeptide which is upregulated in monocytes under conditions of oxidized LDL treatment, the as-filed specification does not provide any written support for the claimed DNA. The only closest relevant description of SEQ ID NO: 1 is provided on page 118 which indicates:

"The fchd605 gene produced a 1.5kb mRNA that is up-regulated after 5 hours treatment with oxidized LDL, and to lesser degree with native LDL, as compared to untreated monocytes. The amplified DNA was sequence and used to recover a cDNA of approximately 2.2kb, which was sequenced to reveal a partial open reading frame of approximately 258 bp, encoding approximately 86 amino acids. The DNA sequence and encoded amino acid sequence from the fchd605 gene is shown in FIG.5".

Applying an analysis of the above paragraph, it is apparent that SEQ ID NO: 10 consist of only 156 amino acid residues, however, the newly amended and added claims recite that SEQ ID NO: 10 consists of 157 amino acid residues. Even if the claims are amended to indicate that SEQ ID NO: 10 consists of 156 amino acid residues, neither the cited paragraph on page 118 of the as-filed specification nor the entire as-filed specification provides any written description of any and/or all DNA that encodes a fchd605 protein which is upregulated in monocytes under conditions of oxidized LDL treatment. The upregulation of a specifically named mRNA or cDNA of approximately 2.2kb after 5 hours treatment with oxidized LDL as supported by the as-filed specification is not the same as claiming a DNA coding for at least amino acids 71-157 of SEQ ID NO: 10 which is upregulated in monocytes under conditions of oxidized LDL treatment,

let alone a claim directed any and/or all DNA coding for any fchd605 polypeptide which is upregulated in monocytes under conditions of oxidized LDL treatment (with respect to claim 105),

Weighing all factors in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that application was in possession of the genus which comprises nucleotides 211-468 of SEQ ID NO: 9. Note that claiming a full-length coding sequence, gene, regulatory sequences, and unrelated cDNA sequences that achieve a result without defining what means will do so is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). In view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed genus other than a DNA sequence consisting of nucleotides 211-468 of SEQ ID No: 9.

Claims 103, and 105-117 are also rejected under 35 U.S.C. 112, first paragraph because the specification is only enabling for claimed invention as recited in claim 104. The specification is not enabling for the claimed subject matter being sought in claim 103, and claims dependent therefrom.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Specifically, since the claimed invention is not supported by a sufficient written description (for possessing of the genus of polynucleotide sequences as recited in the claims) for the reasons set forth above, one skilled in the art would not known how to use and make the claimed invention so that it would operate as intended without undue experimentation.

Claim 104 is allowable because the prior art of record does not teach or suggest the polynucleotide as recited in the claim.

Applicant's response (pages 4-8) has been considered by the examiner but is not found persuasive for the reasons set forth in the stated rejection. More specifically, applicants asserted that in view of the amendment

to the claims, all rejections should be withdrawn. However, the amended and added claims as pending remain subjected to the grounds of rejection as indicated above.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Kimberly Davis, whose telephone number is **(703) 305-3015**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Clark*, may be reached at **(703) 305-4051**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen
Patent Examiner
Art Unit: 1633